Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Pulmonary-Allergy Drugs Advisory Committee (PADAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503) 10903 New Hampshire Avenue, Silver Spring, Maryland December 10, 2015

DRAFT MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Cindy Hong, PharmD

Division of Advisory Committee and Consultant Management Office of Executive Programs CDER, FDA

PULMONARY-ALLERGY DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

John E. Connett, PhD

Professor Division of Biostatistics School of Public Health University of Minnesota Minneapolis, Minnesota

Mitchell H. Grayson, MD

Associate Professor of Pediatrics, Medicine, Microbiology and Molecular Genetics Division of Allergy and Immunology Medical College of Wisconsin MACC Fund Research Center Milwaukee, Wisconsin

Francis X. McCormack, MD

Taylor Professor and Director Division of Pulmonary, Critical Care, and Sleep Medicine University of Cincinnati School of Medicine Cincinnati, Ohio

Dennis R. Ownby, MD

(Chairperson)
Professor of Pediatrics
Division of Allergy, Immunology, and
Rheumatology
Georgia Regents University
Augusta, Georgia

Steve N. Georas, MD

Professor of Medicine Division of Pulmonary and Critical Care Medicine University of Rochester Medical Center Rochester, New York

Michelle Harkins, MD

Associate Professor of Medicine
University of New Mexico
Division of Pulmonary, Critical Care and Sleep
Medicine
Albuquerque, New Mexico

Elaine H. Morrato, DrPH, MPH

Associate Professor Department of Health Systems Management and Policy of Colorado Anschutz Medical Campus Colorado School of Public Health Aurora, Colorado

James M. Tracy, DO

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DRAFT MEETING ROSTER (cont.)

Yanling Yu, MS, PhD

(Consumer Representative)

President and Co-founder Washington Advocates for Patient Safety Seattle, Washington

DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE MEMBERS (Voting)

Kelly Besco, PharmD, FISMP, CPPS

Health-System Medication Safety Coordinator **Ohio-Health Pharmacy Services** Dublin, OH

Tobias Gerhard, PhD, RPh

Associate Professor Rutgers University Department of Pharmacy Practice and Administration Ernest Mario School of Pharmacy New Brunswick, NJ

Jeanmarie Perrone, MD, FACMT

Professor, Emergency Medicine Director, Division of Medical Toxicology Department of Emergency Medicine Perelman School of Medicine at the University of Pennsylvania Philadelphia, Pennsylvania

TEMPORARY MEMBERS (Voting)

George Caleb Alexander, MD, MS

Co-Director, Johns Hopkins Center for Drug Safety University of Kentucky Medical Center and Effectiveness Johns Hopkins Bloomberg School of Public Health Lexington, Kentucky Baltimore, Maryland

Raeford E. Brown, Jr. MD, FAAP

Associate Professor of Epidemiology and Medicine Professor of Anesthesiology and Pediatrics Kentucky Children's Hospital

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DRAFT MEETING ROSTER (cont.)

Bruce Carleton, PharmD

Director, Pharmaceutical Outcomes Programme BC Children's Hospital

Professor of Paediatrics, Population & Public

Health, Pharmaceutical Sciences

Co-Chair, Division of Translational Therapeutics

Department of Pediatrics, Faculty of Medicine

University of British Columbia

Senior Clinician Scientist, Child & Family

Research Institute

Vancouver, British Columbia

Robert Dracker, MD

Director

Summerwood Pediatrics Infusacare Medical Services

Liverpool, New York

Randall P. Flick, MD, MPH

Associate Professor of Anesthesiology and Pediatrics Division of Anesthesiology

Mayo Clinic

Rochester, Minnesota

Sonia Hernandez-Diaz, MD, DrPH

Professor of Epidemiology Harvard T.H. Chan School of Public Health Boston, Massachusetts

J. Steven Leeder, PharmD, PhD

Marion Merrell Dow/Missouri Endowed Chair in Pediatric Clinical Pharmacology Director, Division of Clinical Pharmacology, Toxicology and Therapeutic Innovation Department of Pediatrics

Children's Mercy Hospital

Kansas City, Missouri

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Professor of Clinical Pediatrics

SUNY Stony Brook

Stony Brook, New York

Maureen Finnegan, MD

Associate Professor

Dept. of Orthopaedic Surgery

University of Texas Southwestern Medical Center

Dallas, Texas

Lorraine J. Gudas

Professor and Chairman

Department of Pharmacology

Weill Cornell Medical College of Cornell University

Weill Cornell Medicine

New York, New York

Mark Hudak, MD

Professor and Chairman of Pediatrics

University of Florida College of Medicine -

Jacksonville

Jacksonville, Florida

Melanie Dawn Nelson, PhD

(Patient Representative)

Mount Pleasant, Michigan

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DRAFT MEETING ROSTER (cont.)

Ruth M Parker, MD

Prof of Medicine, Pediatrics, and Public Health Emory University School of Medicine Atlanta, Georgia

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Associate Professor Internal Medicine and **Pediatrics** Institute for Medicine and Public Health Vanderbilt University Staff Physician VA Tennessee Valley Healthcare System Nashville, Tennessee

Gary A. Walco, PhD, ABPP

Professor of Anesthesiology & Pain Medicine Adjunct Professor of Pediatrics and Psychiatry University of Washington School of Medicine Director of Pain Medicine Seattle Children's Hospital Seattle, Washington

Maria Pruchnicki, PharmD, BCPS, BCACP, CLS

Associate Professor of Clinical Pharmacy The Ohio State University College of Pharmacy Specialty Practice Pharmacist, Ambulatory Care The Ohio State University Wexner Medical Center Columbus, Ohio

Maria E. Suarez-Almazor, MD, PhD

Barnts Family Distinguished Professor Section of Rheumatology & Clinical Immunology UT MD Anderson Cancer Center Houston, Texas

Michael Geary White, MD, PhD, FACC, FAAP

Staff Pediatric Cardiologist Ochsner Clinic Foundation New Orleans, Louisiana

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Stuart Green, MD

Vice President Respiratory and Immunology Merck Research Laboratories Rahway, New Jersey

FDA PARTICIPANTS (Non-Voting)

Sally Seymour, MD

Deputy Director for Safety Division of Pulmonary, Allergy, and Rheumatology Division of Anesthesia, Analgesia, and Addiction **Products** Office of Drug Evaluation II (ODE-II)

Office of New Drugs (OND)

CDER, FDA

Judith A. Racoosin, MD, MPH

Deputy Director for Safety

Products

ODE-II, OND, CDER, FDA

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DRAFT MEETING ROSTER (cont.)

CDR David Moeny, RPh, MPH

Deputy Director
Division of Epidemiology II
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Office of Surveillance and Epidemiology
CDER, FDA

Steven Adah, PhD

Interdisciplinary Scientist Team Lead Division of Nonprescription Drug Products Office of Drug Evaluation IV (ODE-IV) OND, CDER, FDA